The new claims generally correspond to the old, canceled claims as follows.

New claims	Old claims
29-31	3-5
32	9
33-38	11-16

REMARKS

Claims 29-38 remain in this case, claim 37 having been restricted out pursuant to a restriction requirement.

Applicants confirm the election of Species III and A, claims 1-5, 7,9, 11-14, 16-25 and 27.

The claims have been rejected as being indefinite. The claims have been amended to remove this basis for rejection. The claims have been rejected as anticipated by one or more of the patents to Edwin and Ragheb or as being obvious over Ragheb in view of the patents to Kropf or Wright.

Claim 28 has been written to more specifically define the present invention. Support for claim 28 can be found at page 2, line 27-page 3, line 2; page 7, line 29-page 8, line 8; page 9, line 2; and page 11, lines 18-18.

The Cited Art

Edwin U.S. Patent No. 6,358,276 discloses various embodiments of coiled, tubular stents used to carry a liquid. The liquid can be used to carry heated or cooled or radioactive fluid through the stent. Drugs may be delivered by filling the stent with a drug and allowing the drug to pass through openings or pores in, for example, ePTFE. (Column 2, lines 41-54; figs. 9 and 10.) The figs. 9-10 embodiment discloses a coiled support wire 94 housed within a hollow ePTFE 92. During use, a fluid may be directed to the pathway 96 defined between support wire 94 and ePTFE 92.

Ragheb U.S. Patent No. 5,873,904 discloses a medical device 10 including a structure 12, typically a vascular stent 12, composed of an elastic/non-elastic, biodegradable/non-biodegradable base material 14, such as stainless steel, nitinol, polymers, etc. Stent 12 is shown to have several layers of materials coated thereon. At least one layer 18 of a bioactive material is on the surface of stent 12. An outer porous layer 20 is on layer 18 to provide controlled release of the bioactive material. A porous/non-porous layer 20 is on layer 18 to provide controlled release of the bioactive material. A porous/non-porous layer 16 may be used between the bioactive layer 18 and stent 12. A second

bioactive layer 22 may be used between porous layer 20 and bioactive layer 18; if so, an inner porous layer 24 may be used between the bioactive layers 18, 22.

Kropf U.S. Patent No. 4,760,849 discloses a ladder type stent.

The Cited Art Distinguished

Independent **claim 28** is allowable over the cited art for a number of reasons. **Edwin** does not disclose a catheter-releasable, patient-implantable device, but rather something quite different. It would not have been obvious to modify the structure of Edwin to arrive at a catheter-releasable, patient-implantable device because doing so would destroy its basic functionality of flowing a liquid through the device. **Ragheb** teaches coating the stent body with one or more layers. There would have been no reason to modify the layered structure of Ragheb because the purpose of space 96 of Edwin is to permit fluid flow therethrough, a feature foreign to Ragheb. Also, there is nothing in the art which suggests it would be desirable to replace support wire 94 of Edwin with the ladder type stent of **Kropf**.

Independent claim 28 has also been written to recite "an NO generator located entirely within the porous tubular graft material." It has been found that nitric oxide (NO) is useful to reduce restenosis. See **Exhibit A**, John B. Cooke MD PhD, *Nitric Oxide and Restenosis, A Report For Vascular Architects*, Sept. 16, 2002. However, the testing discussed at **Exhibit B,** Junghan Yoon, et al, *Local Delivery of Nitric Oxide from an Eluting Stent to Inhibit Neointimal Thickening in a Porcine Coronary Injury Model, Yonsei Med J*, Vol. 43, No. 2, pp.242-251, 2002, discloses that coating stents with an NO generator incorporated into a polymer, similar to the structure shown in Ragheb, was not an effective method for delivery of NO. "However, this sodium nitroprusside-eluting stent failed to reduce chronic neointima thickening in the porcine coronary stent injury model." Exhibit B, page 250.

In contrast, applicants have found through experimentation that a stent graft made according to claim 28 (**Exhibit C**, aSpire® covered stent Product Literature) released NO at a therapeutically effective level for over 60 days. It is believed that this extended-length release period is due to the containment of the NO generator within the porous tubular graft material. See **Exhibit D** (declaration of Kirti Kamdar describing the experiment) and **Exhibits E and F** (plots of NO vs. time for the experiment). While the Ragheb patent may disclose that nitric oxide may be used as a bioactive

material, column 10, lines 57-67, the art fails to recognize that there would be an advantage in using an NO generator within a porous tubular graft material as presently claimed.

Accordingly, claim 28 is allowable over the cited art.

The dependant claims are directed to specific novel subfeatures of the invention and are allowable for that reason as well as by depending from novel parent claims.

CONCLUSION

In light of the above remarks and the amendments to the claims, applicants submit that the application is in condition for allowance and action to that end is urged. If the Examiner believes a telephone conference would aid the prosecution of this case in any way, please call the undersigned at (650) 712-0340.

Respectfully submitted,

HAYNES BEFFEL & WOLFELD LLP

Date: 23 January 2003

By: _____

James F. Hann, Reg. No. 29,719

HAYNES BEFFEL & WOLFELD LLP
P.O. Box 366
Half Moon Bay, CA 94019
Telephone: 650-712-0340/Facsimile: 650-712-0263

Exhibits: A: John B. Cooke MD PhD, *Nitric Oxide and Restenosis, A Report For Vascular Architects*, Sept. 16, 2002.

B: Junghan Yoon, et al, *Local Delivery of Nitric Oxide from an Eluting Stent to Inhibit Neointimal Thickening in a Porcine Coronary Injury Model,* Yonsei Med J, Vol. 43, No. 2, pp.242-251, 2002.

C: aSpire® covered stent Product Literature

D: Declaration of Kirti Kamdar

E: Elution Data (the results of Groups 1 and 2 plotted separately)

F: T 1/2 (single plots for Group 1 and 2 plus a best-fit curve)